

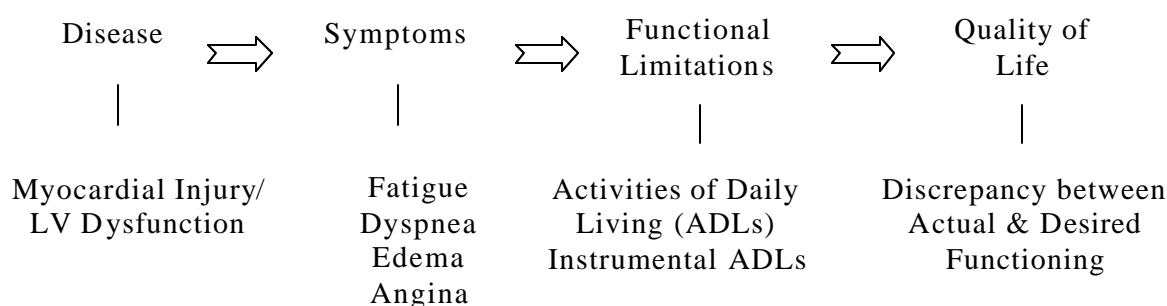


COURAGE Chronicle

February / March 2001

The Importance of Quality of Life and Economic Analysis in the COURAGE Trial

In recent years there has been increasing interest in examining health related quality of life (HRQOL) and economics in clinical trials. HRQOL is of interest because this is, quite often, what is most important to patients. Economics is important because in the current environment different health services compete for limited funds. Thus, forms of therapy that are cost-effective are more likely to be reimbursed and therefore used. We can think of a therapy being cost-effective when it offers good value, or is worth what we are paying for it. A schematic for how HRQOL relates to disease progression follows:



From this graph we can see that quality of life is intrinsically related to disease progression, and not distanced from it. Economics and HRQOL are intrinsic parts of the COURAGE trial.

HRQOL and utility, an overall measure of quality of life for the cost-effectiveness aspect of the trial, are being collected on specialized computers, the Pentablot. This approach allows unique information, especially on utility, to be captured. At the end of the trial, the various QOL scores for all patients will be analyzed by treatment assignment, offering a detailed assessment of the benefit of percutaneous coronary intervention. Let's all work together to collect the best possible quality of data.

Questionnaire

The study leadership would like to thank all the coordinators who completed the questionnaire handed out at the annual meeting. Most of you found the various coordinating centers responsive although sometimes we did not return phone calls quickly enough. We will try to do better. Thank you also for your suggestions about the newsletters and routine reports.

For the Pentablot, sites were split in patient preferences: It took patients, on average, 55-60 minutes to complete the questionnaires for the initial use and 40 minutes for subsequent uses. About **57 percent of the sites found that the Pentablot interfered minimally or not at all with other activities**, while only 17 percent of the sites found excessive interference. If you are among the sites that have had trouble with the Pentablot, consider implementing some of the following strategies other sites have found helpful:

- Sit and review the questions on the Pentablot with the patient at baseline and, if possible, at the one month visit.
- At subsequent visits (the third month and beyond), review the first questionnaire then leave the patient alone.
- Emphasize to patients that they should NOT review answers.
- Ask patients to come in 30 minutes prior to their appointment as patients find completion afterward is a "hassle".
- Break up the time using the Pentablot into smaller chunks.
- Have patients eat breakfast/coffee while using the Pentablot.
- Have patients use the Pentablot while you gather meds.

COURAGE Pharmacy Issues**US Imdur Update**

Good news – we have just received a new supply of Imdur 30mg and 60mg tablets from Key Pharmaceutical. As soon as it is processed we will send an initial supply to each site.

Notification of Expiring Study Drug

In response to requests we have received from a number of sites, the COURAGE PCC will be establishing procedures whereby the Receiving Person (person to whom the drug is shipped) and the Site Coordinator at each site will receive a letter notifying them when study drugs are scheduled to expire.

Because a six-month supply of study drug may be dispensed at later follow-up visits, sites will be notified **SEVEN** months prior to the expiration date. The initial notice will provide a complete list of all study drugs that have expired or will expire within the next seven months.

SAE Reporting Revisited

There still seems to be a little confusion over when to complete a COURAGE Serious Adverse Event (SAE) Report (Form 18). In the COURAGE Trial you are asked to fill out an SAE Report **ONLY** if the event is **SERIOUS** and **POSSIBLY RELATED TO ONE OF THE DONATED STUDY DRUGS OR DEVICES** (these are all listed on the SAE Report). The definition we use for **SERIOUS** is any event that results in one of the following patient outcomes: death; persistent/significant disability; hospitalized (initial or prolonged); life-threatening; congenital anomaly; event significant for other reason; development of cancer; and overdose of drug.

The following SAEs are **NOT** to be documented on the COURAGE SAE Report (Form 18): a) **Procedure-related SAEs** - should be documented on the PCI Procedure Form (Form 10); and b) **SAEs Unrelated to Study Drugs/Devices or Procedures** - should be documented on one or more of the following forms: Hospitalization (Form 11); Suspected MI Event (Form 11A); or Report of Death (Form 19). Questions? Call the PCC (505-248-3203), or a Co-Chair's office (Syracuse: 800-215-7330; or San Antonio: 210-617-5288) if you have any questions.

**PATIENT RANDOMIZATION UPDATE**

| | | To Date | Since Annual Meeting |
|-----|---|------------|----------------------------|
| 671 | Audie L. Murphy VAMC – San Antonio | 120 | 11 |
| 202 | London Health Sciences Centres | 94 | 12 |
| 203 | Montreal Heart Institute | 50 | 4 |
| 580 | Houston VA Medical Center | 46 | 0 |
| 558 | Durham VA Medical Center | 39 | 2 |
| 506 | Ann Arbor VA Medical Center | 39 | 1 |
| 205 | Queen Elizabeth II HSC | 36 | 2 |
| 209 | Sunnybrook & Women's College HSC | 32 | 2 |
| 663 | Seattle VA Medical Center | 31 | 1 |
| 598 | John C. McClellan VA – Little Rock | 30 | 0 |
| 306 | Mayo Clinic—Rochester | 29 | 3 |
| 596 | Lexington VA Medical Center | 29 | 3 |
| 200 | Foothills Hospital | 28 | 3 |
| 630 | New York VA Medical Center | 28 | 1 |
| 313 | University of Oklahoma | 26 | 0 |
| 312 | University of Michigan Medical Center | 25 | 2 |
| 501 | Albuquerque VA Medical Center | 25 | 1 |
| 584 | Iowa City VAMC/Univ. of Iowa Hospital | 21 | 1 |
| 308 | Mid America Heart Institute/Shawnee Mission | 20 | 0 |
| 304 | Emory University Hospital | 19 | 0 |
| 212 | Vancouver Hospital & Health Science Centre | 18 | 0 |
| 210 | The Toronto Hospital | 19 | 1 |
| 648 | Portland VA Medical Center | 16 | 1 |
| 207 | St. Paul's Hospital | 16 | 0 |
| 208 | Sudbury Memorial Hospital | 15 | 0 |
| 626 | Nashville VA Medical Center | 15 | 0 |
| 314 | MIMA Century Research Associates | 14 | 4 |
| 204 | St. Michael's Hospital | 14 | 0 |
| 315 | Southern CA Kaiser Permanente Medical Gr. | 13 | 2 |
| 201 | Hamilton General Hospital, McMaster Clinic | 13 | 1 |
| 301 | Boston Medical Center | 13 | 0 |
| 316 | Hartford Hospital | 9 | 1 |
| 211 | University of Alberta Hospital | 9 | 0 |
| 626 | Vanderbilt University Medical Center | 5 | 0 |
| 214 | Hopital du Sacre Coeur | 4 | 0 |
| 318 | University of Maryland | 1 | 1 |
| 317 | University of Rochester | 1 | 0 |
| 318 | University of California—Davis | 0 | 0 |
| *** | All Terminated Sites | 21 | 0 |

Total Patients as of 03/16/2001: - 983

Ordering Additional Study Drug

When ordering additional COURAGE Study Drug, please use the COURAGE Drug Order Form (Form 28). This form can be e-mailed or faxed to the PCC. If you would like an electronic copy of this form e-mailed to you, please contact Bill Gagne at William.gagne@csp.research.med.va.gov or Carol Fye at carol.fye@csp.research.med.va.gov .

The PCC will contact you if any drug ordered is not available. In order to notify you, however, it would be extremely helpful if you would provide both your e-mail address and telephone number on the order form.